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Complete Summary

GUIDELINE TITLE

Blood gas analysis and hemoximetry: 2001 revision and update.

BIBLIOGRAPHIC SOURCE(S)

Blood gas analysis and hemoximetry: 2001 revision and update. Respir Care 2001 May;46(5):498-505. [34 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Pulmonary disease

GUIDELINE CATEGORY

Diagnosis
Evaluation

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Pulmonary Medicine

INTENDED USERS

Respiratory Care Practitioners

GUIDELINE OBJECTIVE(S)

- To improve the consistency and appropriateness of respiratory care and serve as a guide for education and research
- To provide clinical practice guidelines on sampling for arterial or mixed venous blood gas analysis, pH analysis, and hemoximetry

TARGET POPULATION

Neonatal, pediatric, adult, and geriatric patients with the following indications:

- The need to evaluate the adequacy of a patient's ventilatory (partial pressures of carbon dioxide), acid-base (hydrogen ion concentration and partial pressures of carbon dioxide), and/or oxygenation (partial pressures of oxygen and oxyhemoglobin saturation) status, the oxygen-carrying capacity (partial pressures of oxygen, oxyhemoglobin saturation, total hemoglobin, and dyshemoglobin saturations) and intrapulmonary shunt (Q_{sp}/Q_t); The need to quantitate the patient's response to therapeutic intervention (e.g., supplemental oxygen administration, mechanical ventilation) and/or diagnostic evaluation (e.g., exercise desaturation).
- The need to monitor severity and progression of a documented disease process.

INTERVENTIONS AND PRACTICES CONSIDERED

Sampling for arterial or mixed venous blood gas analysis, hydrogen ion concentration analysis, and hemoximetry (i.e., CO-oximetry).

MAJOR OUTCOMES CONSIDERED

- Direct measurement of partial pressures for carbon dioxide and oxygen (PCO_2 and PO_2), and hydrogen ion concentration (pH), total hemoglobin (tHb), oxyhemoglobin saturation (O_2Hb), and saturations of the dyshemoglobins (carboxyhemoglobin, or COHb, and methemoglobin, or metHb), and other calculated or derived values such as plasma bicarbonate and base excess/deficit.

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Consultants to the Working Group may review the initial draft of the guideline. After completion by the Working group, the draft is reviewed by the entire Steering Committee and then by a Review Panel, persons engaged in all facets of the delivery of respiratory care who have volunteered to review drafts of the Guidelines before publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Description:

Analysis of arterial and/or mixed venous blood provides information concerning the oxygenation, ventilatory, and acid-base status of the subject from whom the specimen was obtained. Analysis of samples from other sources (i.e., capillary, peripheral venous, umbilical venous samples, and pH measured from other body fluids) may provide limited information. The variables most generally measured are the partial pressures for carbon dioxide and oxygen (PCO_2 and PO_2), and hydrogen ion concentration (pH). Additional clinically useful variables are the concentration of total hemoglobin (tHb), oxyhemoglobin saturation (O_2Hb), and saturations of the dyshemoglobins (carboxyhemoglobin, or COHb, and methemoglobin, or metHb), and other calculated or derived values such as plasma bicarbonate and base excess/deficit.

Setting:

Analysis should be performed by trained individuals in a variety of settings including, but not limited to:

- Hospital laboratories
- Hospital emergency areas
- Patient-care areas
- Clinic laboratories
- Laboratories in physicians' offices

Limitations of Procedure/Validation of Results:

- Limitations of technique or methodology can limit value of the procedure. Erroneous results can arise from:
    - Sample clotting due to improper anticoagulation or improper mixing
    - Sample contamination by:
        - Air
        - Improper anticoagulant and/or improper anticoagulant concentration
        - Saline or other fluids (specimen obtained via an indwelling catheter)
        - Inadvertent sampling of systemic venous blood
    - Deterioration or distortion of variables to be measured resulting from:
        - Delay in sample analysis
        - Inappropriate collection and handling (Accurate total hemoglobin concentration measurement depends on homogeneous mixture of specimen, appropriate anticoagulant concentration and specimen-size ratio, and absence of contamination of specimen by analyzer solutions or calibration gases. The concentration measured may also be dependent on the method incorporated by the specific analyzer.)
        - Incomplete clearance of analyzer calibration gases and previous waste or flushing solution(s)
    - Hyperlipidemia causes problems with analyzer membranes and may affect CO-oximetry
    - Appropriate sample size is determined by the type of anticoagulant and the sample requirements of the analyzer(s). Attempts should be made to keep sample sizes as small as is technically feasible to limit blood loss, particularly in neonates

    - Some calculated values may be in error (e.g., calculated oxygen saturation may not reflect oxyhemoglobin saturation in the presence of carboxyhemoglobin and/or methemoglobin and with changes in 2,3 DPG concentration)
    - Arterialized capillary samples may be adequate to assess acid-base disorders but may not adequately reflect patient oxygenation
    - The laboratory must have a defined procedure for temperature correction of the measured results. Errors in the measurement of the patient's temperature may cause erroneous temperature-corrected results. If temperature-adjusted results are reported, the report should be clearly labeled as such, and the measured results at 37 degrees Celsius must also be reported
- Results of analysis can be considered valid if:
    - Analytic procedure conforms to recommended, established guidelines and follows manufacturer's recommendations
    - Results of hydrogen ion concentration-blood gas analysis fall within the calibration range of the analyzer(s) and quality control product ranges. If a result outside of the usual calibration range is obtained (e.g., partial pressures of arterial oxygen measured as 250 torr, but analyzer calibrated to 140 torr), the analyzer should be recalibrated to accommodate this unusual value (using "calibration override" function and high- or 100%-oxygen standard gas)
    - Laboratory procedures and personnel are in compliance with quality control and recognized proficiency testing programs
- If questionable results are obtained and are consistent with specimen contamination:
    - The labeling of the blood sample container should be rechecked for patient's full name, medical record number (patient identifier), date and time of acquisition, and measured FIO2 (or supplemental oxygen liter flow)
    - The residual specimen should be reanalyzed (preferably on a separate analyzer)
    - An additional sample should be obtained if the discrepancy cannot be resolved
    - Results of analysis of discarded samples should be logged with reason for discarding

Assessment of Need:

The presence of a valid indication in the subject to be tested supports the need for sampling and analysis.

Assessment of Quality of Test and Validity of Results:

The consensus of the committee is that all diagnostic procedures should follow the quality model described in the NCCLS GP26 A Quality System Model for Health Care (NCCLS, 940 West Valley Road, Ste. 1400, Wayne, PA 19087-1898; Web site: www.nccls.org). The document describes a laboratory path of workflow model that incorporates all the steps of the procedure. This process begins with patient assessment and the generation of a clinical indication for testing through the application of the test results to patient care. The quality system essentials defined for all healthcare services provide the framework for managing the path of workflow. A continuation of this model for respiratory care services is further described in NCCLS HS4-A A Quality System Model for Respiratory Care (NCCLS, 940 West Valley Road, Ste. 1400, Wayne, PA 19087-1898; Web site: www.nccls.org). In both quality models the patient is the central focus.

- General consideration include:
    - As part of any quality assurance program, indicators must be developed to monitor areas addressed in the path of workflow
    - Each laboratory should standardize procedures and demonstrate intertechnologist reliability. Test results can be considered valid only if they are derived according to and conform to established laboratory quality control, quality assurance, and monitoring protocols
    - Documentation of results, therapeutic intervention (or lack of) and/or clinical decisions based on testing should be placed in the patient's medical record
    - The mode of ventilation, the oxygen concentration, and the oxygen delivery device and the results of the pretest assessment should be documented
    - Report of test results should contain a statement by the technician performing the test regarding test quality (including patient understanding of directions and effort expended) and, if appropriate, which recommendations were not met
    - Test results should be interpreted by a physician, taking into consideration the clinical question to be answered
    - Personnel who do not meet annual competency requirements or whose competency is deemed unacceptable as documented in an occurrence report should not be allowed to participate, until they have received remedial instruction and have been re-evaluated
    - There must be evidence of active review of quality control, proficiency testing, and physician alert, or 'panic' values, on a level commensurate with the number of tests performed
- Blood gas-hydrogen ion concentration analysis and hemoximetry are beneficial only if no preanalytical error has occurred
- Considerations related to equipment quality control and control materials:
    - For internal-equipment quality control using commercial controls:
        - Establish the mean and standard deviation (SD) for each constituent (i.e., hydrogen ion concentration, partial pressures for carbon dioxide and oxygen) in each level for a new lot number of commercial quality control material prior to expiration of the old lot number. The laboratory director or designee should determine the acceptable range for quality control results based on statistically relevant or medical-needs criteria
        - The frequency of each control run and number of levels is dependent on regulatory requirements and manufacturer's recommendations beyond a minimum of 1 level every 8 hours and 2 levels each day that the instrument is in operation
        - Quality control results outside predefined acceptability limits should trigger equipment troubleshooting. Quality control must be verified to be "in control" prior to analysis of specimens. Appropriate documentation of actions taken and results of verification are required

        - Duplicate specimen analysis (i.e., twice on one instrument or once on two instruments) may also be performed on a regular basis as an additional method of quality control. Duplicate analysis of the same analytes on different models of equipment is generally required by accrediting agencies
        - Tonometry is the reference procedure to establish accuracy for blood partial pressures for oxygen and partial pressures for carbon dioxide. If issues of true accuracy arise, tonometry should be available
        - Electronic quality control monitors only the equipment performance. The use of nonelectronic controls at periodic intervals should also be employed to evaluate the testing process
        - Record keeping. Summarize all quality control data for a specified lot number. Maintain and generate reports according to regulatory and institutional policy
    - External quality control or proficiency testing considerations:
        - Proficiency testing is required by the Clinical Laboratory Amendments of 1988 (CLIA'88) for each regulated analyte. Specimens of unknown values from an external source are to be analyzed a minimum of 3 times a year
        - Proficiency-testing materials should be obtained from an approved source to meet regulatory requirements
        - The proficiency testing survey report should be carefully reviewed by the medical director and laboratory supervisor. If the results are suboptimal, the medical director and supervisor should promptly review their equipment, procedures, and materials to ascertain the cause of the poor performance
    - With new equipment installation:
        - CLIA '88 requires the evaluation of equipment accuracy and imprecision prior to analysis of patient samples
        - Tonometry is the reference method for establishing accuracy for partial pressures of arterial oxygen and partial pressures of carbon dioxide in arterial gas, but unless the entire tonometry process is of the highest quality, it, too, can have errors
        - When an existing instrument is replaced, duplicate analysis must be performed to compare the new instrument to the existing instrument
    - Calibration verification:
        - Calibration verification is performed prior to initial use and at 6-month intervals. Calibration verification is completed by analyzing a minimum of 3 levels of control material to verify the measuring range of the analyzer. A fourth level should be considered if samples with high oxygen levels are analyzed on the instrument
        - Frequency of calibration verification may vary according to regulatory agencies under which the laboratory is accredited or licensed [i.e., College of American Pathologists (CAP), CLIA'88 or Joint Commission on Accreditation of Healthcare Organizations (JCAHO)]
- Testing (analytical phase) is carried out according to an established proven protocol, conforming to manufacturer recommendations; The following

aspects of analysis should be monitored and corrective action taken as indicated:

- Detection of presence of air bubbles or clots in specimen, with evacuation prior to mixing and sealing of syringe
- Assurance that an uninterrupted (i.e., solid or continuous) sample is aspirated (or injected) into analyzer and that all of the electrodes are covered by the sample (confirmed by direct viewing of sample chamber if possible
- Assurance that 8-hour quality control and calibration procedures have been completed and that instrumentation is functioning properly prior to patient sample analysis
- Assurance that specimen was properly labeled, stored, and analyzed within an acceptable period of time

- Post-testing (post-analytical phase). The results should validate or contradict the patient's clinical condition (i.e., the basis for ordering the test)
    - Documentation of results, therapeutic intervention (or lack of), and/or clinical decisions based upon the hydrogen ion concentration-blood gas measurements should be available in the patient's medical record and/or be otherwise readily accessible (e.g., at the testing area) for at least 2 years
    - Reference intervals and 'critical values' must be determined for each analyte prior to sample analysis. If the reference interval is determined by transference, the interval should be validated. Defining and determining reference intervals is described in NCCLS document C24-A2 ((NCCLS, 940 West Valley Road, Ste. 1400, Wayne, PA 19087-1898; Web site: www.nccls.org)

Resources:

Federal regulations, stipulate that requirements relative to personnel (levels of education and training), documentation procedures and equipment be fulfilled. Blood gas instrumentation is classified as being either moderately or highly complex. Persons performing blood gas analysis should be conversant with applicable federal regulations (CLIA'88) and appropriately qualified.

- Recommended Equipment:
    - Automated or semiautomated hydrogen ion concentration -blood gas analyzer with related calibration gases, electrodes, membranes, electrolytes, reagents, and accessories
    - Fixed, multiple wavelength spectrophotometer (hemoximeter or CO-oximeter) or other device for determining total hemoglobin and its components
    - Protective eye wear as necessary and outerwear, protective gloves, impenetrable needle container, facemask and/or face-shield
    - Quality control and proficiency testing materials
- Personnel:
    - The following recommendations are for tests of moderate complexity, as designated by CLIA '88. Persons at either of the levels described should perform hydrogen ion concentration -blood gas analysis under the direction and responsibility of a laboratory director and technical consultant (may be the same individual) who possess at least a

baccalaureate degree and who have specific training in blood gas analysis and interpretation:

- Level I: Personnel should be specifically trained in hydrogen ion concentration-blood gas analysis, oxygen delivery devices, and related equipment, record keeping, and hazards and sources of specimen and handler contamination(s) associated with sampling and analysis. Such persons should be, at minimum, high school graduates (or equivalent) with strong backgrounds in mathematics, and preferably with one or more years of college courses in the physical and biological sciences. Such persons must have documented training and demonstrated proficiency in hydrogen ion concentration-blood gas analysis, preventive maintenance, troubleshooting, instrument calibration, and awareness of the factors that influence test results, and the skills required to verify the validity of test results through the evaluation of quality-control sample values, prior to analyzing patient specimens and reporting results. Performance of hydrogen ion concentration-blood gas analysis must be supervised by a Level-II technologist.
- Level II: Level-II personnel supervise Level-I personnel and are health care professionals specifically trained (with proven, documented proficiency) in all aspects of blood gas analysis and hemoximetry:
    - Quality control, quality assurance, and proficiency testing
    - Operation and limitations, including instrument troubleshooting and appropriate corrective measures
    - Level-II personnel should be cognizant of various means for specimen collection and the causes and impact of preanalytical and instrument error(s)
    - Level-II personnel should be trained in patient assessment, acid-base and oxygenation disorders, and diagnostic and therapeutic alternatives. A baccalaureate, or higher, degree in the sciences or substantial experience in pulmonary function technology is preferred. Although, 2 years of college in biological sciences and mathematics, plus 2 years of training and experience, or equivalent may be substituted for personnel supervising arterial hydrogen ion concentration-blood gas analysis. A recognized credential Medical Technologist (MT), Medical Laboratory Technician (MLT), CRT, RRT, Certified Pulmonary Function Technologist (CPFT) or Registered Pulmonary Function Technologist (RPFT)] is strongly recommended

Monitoring:

Monitoring of personnel, sample handling, and analyzer performance to assure proper handling, analysis, and reporting should be ongoing, during the process.

Frequency:

Frequency of execution of procedures depends upon the sample load of the laboratory and the requirements of agencies that specify quality control maneuvers.

Infection Control:

- The staff, supervisors, and physician-directors associated with the pulmonary laboratory should be conversant with the document titled "Guideline for Isolation Precautions in Hospitals" made by the Centers for Disease Control and Prevention and the Hospital Infection Control Practices Advisory Committee (HICPAC), and develop and implement policies and procedures for the laboratory that comply with its recommendations for "Standard Precautions" and "Transmission-Based Precautions"
- The laboratory's manager and its medical director should maintain communication and cooperation with the institution's infection control service and the personnel health service to help assure consistency and thoroughness in complying with the institution's policies related to immunizations, post-exposure prophylaxis, and job- and community-related illnesses and exposures
- Primary considerations include:
    - Adequate handwashing
    - Provision of prescribed ventilation with adequate air exchanges
    - Careful handling and thorough cleaning and processing of equipment
    - The exercise of particular care in scheduling and interfacing with the patient in whom a diagnosis has not been established

Age-Specific Issues:

This document applies to samples from neonatal, pediatric, adult, and geriatric populations.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Not specifically stated for each recommendation.

The guideline is developed from a thorough review of the literature, surveys of current practice, and the expertise of the members of the Working Group.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Direct measurement of partial pressures for carbon dioxide and oxygen (PCO_2 and PO_2), and hydrogen ion concentration (pH), total hemoglobin (tHb), oxyhemoglobin saturation (O_2Hb), and saturations of the dyshemoglobins (carboxyhemoglobin, or COHb, and methemoglobin, or metHb), and other calculated or derived values such as plasma bicarbonate and base excess/deficit.

- Effective monitoring of adequacy of a patient's ventilatory (partial pressure of carbon dioxide in arterial gas), acid-base (hydrogen ion concentration and partial pressure of carbon dioxide in arterial gas), and/or oxygenation (partial pressure arterial oxygen and oxyhemoglobin saturation) status, the oxygen-carrying capacity (partial pressure arterial oxygen, oxyhemoglobin saturation, total hemoglobin, and dyshemoglobin saturations) and intrapulmonary shunt (Q_{sp}/Q_t); patient's response to therapeutic intervention (e.g., supplemental oxygen administration, mechanical ventilation) and/or diagnostic evaluation (e.g., exercise desaturation); severity and progression of a documented disease processes.

POTENTIAL HARMS

Hazards/Complications:

- Infection of specimen handler from blood carrying the human immunodeficiency virus, or HIV, hepatitis B, other blood-borne pathogens.
- Inappropriate patient medical treatment based on improperly analyzed blood specimen or from analysis of an unacceptable specimen or from incorrect reporting of results.

CONTRAINDICATIONS

CONTRAINDICATIONS

Contraindications to performing pH-blood gas analysis and hemoximetry include:

- An improperly functioning analyzer

- An analyzer that has not had functional status validated by analysis of commercially prepared quality control products or tonometered whole blood or has not been validated through participation in a proficiency testing program(s)

- A specimen that has not been properly anticoagulated

- A specimen containing visible air bubbles

- A specimen stored in a plastic syringe at room temperature for longer than 30 minutes, stored at room temperature for longer than 5 minutes for a shunt study, or stored at room temperature in the presence of an elevated leukocyte or platelet count (PaO_2 in samples drawn from subjects with very high leukocyte counts can decrease rapidly. Immediate chilling and analysis is necessary)

- An incomplete requisition that precludes adequate interpretation and documentation of results and for which attempts to obtain additional information have been unsuccessful. Requisitions should contain:
    - Patient's name or other unique identifier, such as medical record number; birth date or age, date and time of sampling
    - Location of patient
    - Name of requesting physician or authorized individual
    - Clinical indication and tests to be performed;
    - Sample source (arterial line, central venous catheter, peripheral artery)
    - Respiratory rate and for the patient on supplemental oxygen fractional concentration of inspired oxygen (FIO_2) or oxygen flow
    - Ventilator settings for mechanically ventilated patients (tidal volume, respiratory rate, FIO_2, mode)
    - Signature of person who obtained sample

  It may also be useful to note body temperature, activity level, and working diagnosis. Test requisition should be electronically generated or handwritten and must be signed by the person ordering the test. Oral requests must be supported by written authorization within 30 days.

- An inadequately labeled specimen lacking the patient's full name or other unique identifier (e.g., medical record number), date, and time of sampling

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Blood gas analysis and hemoximetry: 2001 revision and update. Respir Care 2001 May;46(5):498-505. [34 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 May

GUIDELINE DEVELOPER(S)

American Association for Respiratory Care - Professional Association

SOURCE(S) OF FUNDING

American Association for Respiratory Care (AARC)

GUIDELINE COMMITTEE

Pulmonary Function Testing Clinical Practice Guidelines Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Susan Blonshine BS, RRT, RPFT; Catherine M Foss BS, RRT, RPFT; Carl Mottram BA, RRT, RPFT, Chair; Gregg Ruppel Med, RRT, RPFT; Jack Wanger MS, RRT, RPFT

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates of a previously issued version (Sampling for arterial blood gas analysis. Respir Care 1992 Aug;37[8]:913-7).

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Association for Respiratory Care (AARC) Web site.

Print copies: Available from AARC, CPG Desk, 11030 Ables Ln, Dallas, TX 75229-4593.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on November 30, 1998. The information was verified by the guideline developer on December 15, 1998. This summary was updated by ECRI on August 24, 2001. The updated information was verified by the guideline developer as of October 17, 2001.

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